I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on

TOWNSEND and TOWNSEND and CREW LLP

By: Jangundu

Attorney Docket No.: 015280-368240US Client Reference No.: E-268-1997/2-US-

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Jay A. Berzofsky et al.

Application No.: 10/815,340

Filed: March 30, 2004

For: MUCOSAL CYTOTOXIC T LYMPHOCYTE RESPONSES

Confirmation No.: 8261

Examiner: Nicole Kinsey

Art Unit: 1645

INFORMATION DISCLOSURE

STATEMENT UNDER 37 CFR §1.97 and

§1.98

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the references can be found in Parent Application No. 09/508,552, filed March 9, 2000 (now U.S. Patent No. 6,749,856, issued on June 15, 2004; Attorney Docket No. 015280-368200US). It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

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representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that <u>no fee is required</u> for submission of this statement.

However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

Date: March 30, 2007

By:

Nicholas V. Sherbina

Reg. No. 54,443

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NVS:jms 61015199 v1

Subs	titute fo	or form 1449A	&B/PTO			Complete if Known		
						Application Number	10/815,340	
IN	FOF	RMATIC	N DISC	CLOS	URE	Filing Date	March 30, 2004	
S1	STATEMENT BY APPLICANT					First Named Inventor	Berzofsky, Jay A.	
						Art Unit	1645	
	(Use as many sheets as necessary)					Examiner Name	Nicole Kinsey	
Shee	t	1		of	5	Attorney Docket Number	015280-368240US	

			U.S. PATENT D	OCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number Kind Code ^{2 (# known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	4,629,783	12/16/86	Cosand	
	AB	4,943,628	07/24/90	Rosen et al.	
	AC	5,030,449	07/09/91	Berzofsky et al.	
	AD	5,081,226	01/14/92	Berzofsky et al.	THE THE PROPERTY OF THE PROPER
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Initials*	No.¹	Country Code ³	Number ⁴	Kind Code ⁵ (<i>if known</i>)	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	Тв			
	AE	PCT	WO 87/07616		12/17/1987						
	AF	PCT	0 273 716		12/23/1987						
	AG	PCT	WO 94/26785		11/24/1994						
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Examiner	Date	
Signature	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

Substi	tute for form 1449A&B/PTO			Complete if Known		
				Application Number	10/815,340	
INF	ORMATION DIS	CLOS	SURE	Filing Date	March 30, 2004	
ST	ATEMENT BY A	PPLIC	CANT	First Named Inventor	Berzofsky, Jay A.	
				Art Unit	1645	
	(Use as many sheets as I	necessary)		Examiner Name	Nicole Kinsey	
Sheet	2	of	5	Attorney Docket Number	015280-368240US	

		NON PATENT LITERATURE DOCUMENTS							
Examiner Initials *	Cite No. ¹								
	АН	Ahlers et al., "Construction of an HIV-1 Peptide Vaccine Containing a Multideterminant Helper Peptide Linked to a V3 Loop Peptide 18 Inducing Strong Neutralizing Antibody Responses in Mice of Multiple MHC Haplotypes after Two Immunizations," J. Immunol. 150:5647-5665 (1993).							
	Ahlers et al., "Candidate HIV Type 1 Multideterminant Cluster Peptide-P18MN Vaccin Constructs Elicit Type 1 Helper T Cells, Cytotoxic T Cells, and Neutralizing Antibody, Using the Same Adjuvant Immunization," AIDS Res. Hum. Retroviruses 12:259-272 (1996).								
	Allers et al., "Cytokine-in-Adjuvant Steering of the Immune Response Phenotype to HIV-1 Vaccine Constructs," J. Immunol. 158:3947-3958 (1997).								
	AK	Ahlers et al., "Enhanced Immunogenicity of HIV-1 Vaccine Construct by Modification of the native Peptide Sequence," Proc. Natl. Acad. Sci. USA 94:10856-10861 (1997).							
	AL	Belyakov et al., "Mucosal Immunization with HIV-1 Peptide Vaccine Induces Mucosal and Systemic Cytotoxic T Lymphocytes and Protective Immunity in Mice Against Intrarectal Recombinant HIV-Vaccinia Challenge," Proc. Nat. Acad. Sci. 95:1709-1714 (1998).							
	АМ	Berzofsky et al., "Construction of Peptides Encompassing Multideterminant Clusters of Human Immunodeficiency Virus Envelope to Induce In Vitro T Cell Responses in Mice and Humans of Multiple MHC Types," J. Clinical Invest. 88:876-884 (1991).							
	AN	Berzofsky and Berkower, "Novel Approaches to Peptide and Engineered Protein Vaccines for HIB Using Defined Epitopes: Advances in 1994-1995," AIDS 1995 9(A):S143-S157 (1995).							
	AO	Bomsel, "Transcytosis of Infectious Human Immunodeficiency Virus Across a Tight Human Epithelial Cell Line Barrier," <i>Nature Medicine</i> 3:42-47 (1997).							
	АP	Butini et al., "Comparative Analysis of HIV-Specific CTL Activity in Lymphoid Tissue and Peripheral Blood," J. Cellular Biochemistry Abstract Supplement: 147 (1994).							
	AQ	Cranage <i>et al.</i> , "Macaques Infected with Live Attenuated SIVmac are Protected Against Superinfection via the Rectal Mucosa," <i>Virology</i> 229:143-154 (1997).							
Examiner Signature		Date Considered							

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STA	TEMENT B	Y APPLIC	CANT	First Named Inventor	Berzofsky, Jay A.	
				Art Unit	1645	
	(Use as many she	ets as necessary)		Examiner Name	Nicole Kinsey	
Sheet	3	of	5	Attorney Docket Number	015280-368240US	

	NON PATENT LITERATURE DOCUMENTS							
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (bo magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published.						
	AR	di Tommaso et al., "Induction of Antigen-Specific Antibodies in Vaginal Secretions by Using a Nontoxic Mutant of Heat-Labile Enterotoxin as a Mucosal Adjuvant," Infection and Immunity 64:974-979 (1996).						
	AS	Douce et al., "Intranasal Immunogenicity and Adjuvanticity of site-directed mutant derivatives of cholera toxin," Infection and Immunity 65:2821-2828 (1997).						
	AT	Gallichan et al., "Long-Lived Cytotoxic T Lymphocyte Memory in Mucosal Tissues After Mucosal but not Systemic Immunization," J. Exp. Med. 184:1879-1890 (1996).						
	AU	Graham et al., "Candidate AIDS Vaccines," New England Journal of Medicine 333:1331- 1339 (1995).						
	AV	Hale et al., "T Cell Multideterminant Regions in the Human Immunodeficiency Virus Envelope: Toward Overcoming the Problem of Major Histocompatibility Complex Restriction," International Immunology 1:409-415 (1989).						
	AW	Haynes, B.F., "Scientific and Social Issues of Human Immunodeficiency Virus Vaccine Development," Science 260:1279-1286 (1993).						
	AX	Klavinskis et al., "Mucosal or Targeted Lymph Node Immunization of Macaques with a Particulate SIVp27 Protein Elicits Virus-Specific CTL in the Genito-Rectal Mucosa and Draining Lymph Nodes," <i>J. Immunol.</i> 157:2521-2527 (1996).						
	ΑY	Kozlowski et al., "Serum Angiotensin-1 Converting Enzyme Activity Processes a Human Immunodeficiency Virus 1 Gp160 Peptide for Presentation by Major Histocompatibility Complex Class I Molecules," J. Exp. Med. 175:1417-1422 (1992).						
	AZ	Langermann, S., "New Approaches to Mucosal Immunization," Seminars in Gastrointestinal Disease 7:12-18 (1996).						
	BA	Lehner et al., "Protective Mucosal Immunity Elicited by Targeted Iliac Lymph Node Immunization with a Subunit SIV Envelope and Core Vaccine in Macaques," Nature Medicine 2:767-775 (1996).						

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Sheet	4	of	5	Attorney Docket Number	015280-368240US	

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Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²					
	ВВ	Miller et al., "Genital Mucosal Transmission of Simian Immunodeficiency Virus: Animal Model for Heterosexual Transmission of Human Immunodeficiency Virus," J. Virol. 63:4277-4284 (1989).						
	BC	Modrow et al., "Computer- Assisted Analysis of Envelope Protein Sequences of Seven Human Immunodeficiency Virus Isolates: Prediction of Antigenic Epitopes in Conserved and Variable Regions," J. Virol. 61:570-578 (1987).						
***************************************	BD	Musey et al., "HIV-1 Induces Cytotoxic T Lymphocytes in the Cervix of Infected Women," J. Exp. Med. 185:293-300 (1997).						
	BE	Neutra et al., "Antigen Sampling Across Epithelial Barriers and Induction of Mucosal Immune Responses," Annu. Rev. Immunol. 14:275-300 (1996).						
	BF	Parditos et al., "Antibody Responses to Non-Immunogenic Synthetic Peptides Induced by Co-Immunization with Immunogenic Peptides," Immunology 77:262-266 (1992).						
	BG	Parditos et al., "Mucosal Immunization with a Measles Virus CTL Epitope Encapsulated in Biodegradable PLG Microparticles," J. Immun. Meth. 195:135-138 (1996).						
	ВН	Parditos et al., "The Adjuvant Effect of a Non-Toxic Mutant of Heat-Labile Enterotoxin of Escherichia Coli for the Induction of Measles Virus-Specific CTL Responses After Intranasal Co-Immunization with a Synthetic Peptide," Immunology 89:483-487 (1996).						
	BI	Porgador et al., "Intranasal Immunization with CTL Epitope Peptides from HIV-1 or Ovalbumin and the Mucosal Adjuvant Cholera Toxin Induces Peptide-Specific CTLs and Protection Against Tumor Development in Vivo," J. Immunol. 158:834-841 (1997).						
	ВЈ	Shirai <i>et al.</i> , "Broad Recognition of Cytotoxic T Cell Epitopes from the HIV-1 Envelope Protein with Multiple Class I Histocompatibility Molecules," <i>J. Immunol.</i> 148:1657-1667 (1992).						
	BK	Shirai et al., "Helper-Cytotoxic T Lymphocyte (CTL) Determinant Linkage Required for Priming of Anti-HIV CD8+ CTL in Vivo with Peptide Vaccine Constructs," J. Immunol. 152:549-556 (1994).						
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	BL	Takahashi et al., "An Immunodominant Epitope of the Human Immunodeficiency Virus Envelope Glycoprotein Gp160 Recognized by Class I Major Histocompatibility Complex Molecule-Restricted Murine Cytotoxic T Lymphocytes," Proc. Natl. Acad. Sci. USA 85:3105-3109 (1988).					
	ВМ	Takahashi et al., "Induction of Broadly Cross-Reactive Cytotoxic T Cells Recognizing an HIV-1 Envelope Determinant," Science 255:333-336 (1992).					
	BN	Takeshita <i>et al.</i> , "Molecular Analysis of the Same HIV Peptide Functionally Binding to Both a Class I and a Class II MHC Molecule," <i>J. Immunol.</i> 154:1973-1986 (1995).					
	во	Yamamoto et al., "Mutants in the ADP-ribosyltransferase Cleft of Cholera Toxin Lack Diarrheagenicity but retain adjuvanticity," J. Exp. Med. 185:1203-1210 (1997).					
	ВР	Yamamoto et al., "A nontoxic mutant of cholera toxin elicits Th2-type responses for enhanced mucosal immunity," Proc. Natl. Acad. Sci. USA 94:5267-5272 (1997).					

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